

Listing of Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim 1 (currently amended): A method for treating infertility in a subject, the subject having a ratio of T helper 1 (Th1) immune response to T helper 2 (Th2) immune response, the method comprising withdrawing a blood sample from the subject prior to conception and measuring in the subject an in serum or intracellular Th1 immune response and an in serum or intracellular Th2 immune response, administering to the subject prior to conception a Th1 antagonist or a Th2 agonist to reduce the ratio of Th1 immune response to Th2 immune response in the subject to inhibit spontaneous abortion or implantation failure and withdrawing a blood sample from the subject after administering the Th1 antagonist or the Th2 agonist and measuring an in serum or intracellular Th1 immune response and an in serum or intracellular Th2 immune response.

Claim 2 (currently amended): The method of claim 1, wherein the implantation failure occurs after assisted reproductive technology (ART) cycles or ovulation induction cycles.

Claim 3 (currently amended): The method of claim 2, wherein the ART ~~is~~ includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 4 (currently amended): The method of claim 1, wherein the ratio of Th1 immune response to Th2 immune response in the subject is a ratio of absolute cell counts or percentage of a representative population of Th1 cells to a representative population of Th2 cells.

Claim 5 (original): The method of claim 1, wherein the ratio of Th1 immune response to Th2 immune response in the subject is determined by measuring a ratio of the level of a Th1 cytokine to a Th2 cytokine.

Claim 6 (original): The method of claim 5, wherein the levels of Th1 and Th2 cytokines are serum levels.

Claim 7 (original): The method of claim 5, wherein the levels of Th1 and Th2 cytokines are intracellular levels.

Claim 8 (original): The method of claim 1, wherein the method of reducing the ratio of Th1 immune response to Th2 immune response is to reduce the absolute counts of Th1 cells in the subject.

Claim 9 (currently amended): The method of claim 8, wherein the Th1 cell is a TNF- α or IFN- γ expressing CD3+/CD4+ T-cell.

Claim 10 (original): The method of claim 1, wherein the method of reducing the ratio of Th1 immune response to Th2 immune response is to increase the absolute counts of Th2 cells in the subject.

Claim 11 (currently amended): The method of claim 10, wherein the Th2 cell is an IL-4 or IL-10 expressing CD3+/CD8- T-cell.

Claim 12 (original): The method of claim 1, wherein the method of reducing the ratio of Th1 immune response to Th2 immune response is to suppress the Th1 cytokines in the subject.

Claim 13 (original): The method of claim 1, wherein the method of reducing the ratio of Th1 immune response to Th2 immune response is to enhance the level of Th2 cytokines in the subject.

Claim 14 (original): The method of claim 12, wherein the Th1 cytokines are selected from the group consisting of IL-1, IL-2, TNF- α , and IFN- γ .

Claim 15 (original): The method of claim 13, wherein the Th2 cytokines are selected from the group consisting of IL-4, IL-5, IL-6, IL-10.

Claim 16 (original): The method of claim 5, wherein the Th1 to Th2 cytokine ratio is a ratio of IFN- γ to IL-4.

Claim 17 (original): The method of claim 5, wherein the Th1 to Th2 cytokine ratio is a ratio of IFN- γ to IL-10.

Claim 18 (original): The method of claim 5, wherein the Th1 to Th2 cytokine ratio is a ratio of TNF- α to IL-4.

Claim 19 (original): The method of claim 5, wherein the Th1 to Th2 cytokine ratio is a ratio of TNF- α to IL-10.

Claims 20-27 (withdrawn):

Claim 28 (original): The method of claim 12, wherein the method of suppressing the Th1 cytokines is by administering an effective dose of a Th1 cytokine antagonist to the subject.

Claim 29 (original): The method of claim 28, wherein the Th1 cytokine antagonist is an inhibitor of the synthesis of the cytokine.

Claim 30 (original): The method of claim 28, wherein the Th1 cytokine antagonist blocks the binding of the cytokine to its receptor.

Claim 31 (original): The method of claim 28, wherein the Th1 cytokine antagonist inactivates the cytokine by binding to the cytokine.

Claim 32 (original): The method of claim 28, wherein the Th1 cytokine antagonist is a polyclonal antibody.

Claim 33 (original): The method of claim 28, wherein the Th1 cytokine antagonist is a monoclonal antibody.

Claim 34 (original): The method of claim 28, wherein the Th1 cytokine antagonist is a soluble receptor of the cytokine.

Claim 35 (original): The method of claim 28, wherein the Th1 cytokine antagonist is selected from the group consisting of: IL-1 antagonists, IL-2 antagonists, TNF- α antagonists, and IFN- γ antagonists.

Claim 36 (original): The method of claim 35, wherein the TNF- α antagonist is infliximab.

Claim 37 (original): The method of claim 35, wherein the TNF- α antagonist is etanercept.

Claim 38 (original): The method of claim 35, wherein the TNF- α antagonist is D2E7.

Claim 39 (original): The method of claim 35, wherein the TNF- α antagonist is CDP571.

Claim 40 (original): The method of claim 35, wherein the TNF- α antagonist is CDP870.

Claims 41-42 (withdrawn)

Claim 43 (original): The method of claim 1, wherein the treatment of infertility further comprises enhancing embryo implantation, pregnancy, or birth rates of the subject.

Claim 44 (original): The method of claim 1, wherein the treatment of infertility enhances the ability of the subject to carry at least one embryo to term.

Claim 45 (original): The method of claim 1, wherein the subject is a human.

Claim 46 (original): The method of claim 1, wherein the subject has had one or more previous spontaneous abortions or implantation failures.

Claim 47 (currently amended): The method of claim 46, wherein the implantation failures occur after ART cycles or ovulation induction cycles.

Claim 48 (currently amended): The method of claim 47, wherein the ART ~~is~~includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 49 (original): The method of claim 1, wherein the subject undergoes natural conception.

Claim 50 (currently amended): The method of claim 1, wherein the subject undergoes ART cycles or ovulation induction cycles.

Claim 51 (currently amended): The method of claim 50, wherein the ART ~~is~~includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 52 (original): The method of claim 1, wherein the subject undergoes ovulation induction cycles.

Claim 53 (currently amended): A method for treating infertility in a subject by inhibiting spontaneous abortion or implantation failure for enhancing embryo implantation, pregnancy, or birth rates, the method comprising withdrawing a blood sample from the subject prior to conception and measuring an in serum or intracellular Th1 immune response and an in serum or intracellular Th2 immune response and administering a therapeutically effective dosage level of a TNF- α antagonist to the subject prior to conception by the subject and withdrawing a blood sample from the subject after administering the TNF- α antagonist and measuring an in serum or intracellular Th1 immune response and an in serum or intracellular Th2 immune response.

Claim 54 (original): The method of claim 53, wherein the implantation failure occurs after ART cycles.

Claim 55 (currently amended): The method of claim 54, wherein the ART ~~is~~includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 56 (original): The method of claim 53, further enhancing the ability of the subject to carry at least one embryo to term.

Claim 57 (original): The method of claim 53, wherein the subject is a human.

Claim 58 (original): The method of claim 53, wherein the subject has had one or more previous spontaneous abortions or implantation failures.

Claim 59 (original): The method of claim 58, wherein the implantation failures occur after ART cycles.

Claim 60 (currently amended): The method of claim 59, wherein the ART ~~is~~includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 61 (original): The method of claim 53, wherein the subject undergoes natural conception.

Claim 62 (original): The method of claim 53, wherein the subject undergoes ART cycles.

Claim 63 (currently amended): The method of claim 62, wherein the ART ~~is~~includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 64 (original): The method of claim 53, wherein the subject undergoes ovulation induction cycles.

Claim 65 (original): The method of claim 53, wherein the TNF- α antagonist is infliximab.

Claim 66 (original): The method of claim 53, wherein the TNF- α antagonist is etanercept.

Claim 67 (original): The method of claim 53, wherein the TNF- α antagonist is D2E7.

Claim 68 (original): The method of claim 53, wherein the TNF- α antagonist is CDP571.

Claim 69 (original): The method of claim 53, wherein the TNF- α antagonist is CDP870.

Claims 70-72 (withdrawn):

Claim 73 (currently amended): A method of enhancing the ability of a subject to carry at least one embryo to term comprising withdrawing a blood sample from the subject prior to conception and measuring an in serum or intracellular Th1 immune response and an in serum or intracellular Th2 immune response and administering to the subject prior to conception by the subject an effective dose of a TNF- α antagonist to inhibit TNF- α in the subject to inhibit spontaneous abortion or implantation failure and withdrawing a blood sample from the subject after administering the TNF- α antagonist and measuring an in serum or intracellular Th1 immune response and an in serum or intracellular Th2 immune response.

Claim 74 (original): The method of claim 73, wherein the implantation failure occurs after ART cycles.

Claim 75 (currently amended): The method of claim 74, wherein the ART ~~is~~includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 76 (original): The method of claim 73, wherein the subject is a human.

Claim 77 (original): The method of claim 73, wherein the subject has had one or more previous spontaneous abortions or implantation failures.

Claim 78 (original): The method of claim 73, wherein the TNF- α antagonist is infliximab.

Claim 79 (original): The method of claim 73, wherein the TNF- α antagonist is etanercept.

Claim 80 (original): The method of claim 73, wherein the TNF- α antagonist is D2E7.

Claim 81 (original): The method of claim 73, wherein the TNF- α antagonist is CDP571.

Claim 82 (currently amended): The method of claim 73, wherein the TNF- α antagonist is CDP870.

Claims 83-85 (withdrawn):

Claim 86 (previously presented): A method for treating infertility in a subject by inhibiting spontaneous abortion or implantation failure for enhancing embryo implantation, pregnancy, or birth rates, the method comprising administering a therapeutically effective dosage level of infliximab to the subject prior to conception by the subject.

Claim 87 (original): The method of claim 86, wherein the implantation failure occurs after ART cycles.

Claim 88 (currently amended): The method of claim 86, wherein the ART is ~~is~~ includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 89 (original): The method of claim 86, further enhancing the ability of the subject to carry at least one embryo to term.

Claim 90 (original): The method of claim 86, wherein the subject is a human.

Claim 91 (original): The method of claim 86, wherein the subject has had one or more previous spontaneous abortions or implantation failures.

Claim 92 (original): The method of claim 91, wherein the implantation failures occur after ART cycles.

Claim 93 (currently amended): The method of claim 92, wherein the ART ~~is~~includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 94 (original): The method of claim 86, wherein the subject undergoes natural conception.

Claim 95 (original): The method of claim 86, wherein the subject undergoes ART cycles.

Claim 96 (currently amended): The method of claim 95, wherein the ART ~~is~~includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 97 (original): The method of 86, wherein the subject undergoes ovulation induction cycles.

Claim 98 (original): The method of claim 86, wherein the therapeutically effective dosage level of infliximab is from about 3 mg/Kg to about 10 mg/Kg.

Claim 99 (original): The method of claim 86, wherein the administration of infliximab is performed by delivering a therapeutically effective dosage level of infliximab intravenously.

Claim 100 (original): The method of claim 86, wherein the administration of infliximab is performed by delivering a therapeutically effective dosage level of infliximab subcutaneously.

Claim 101 (original): The method of claim 86, wherein the administration of infliximab is performed by delivering a therapeutically effective dosage level of infliximab vaginally.

Claim 102 (original): The method of claim 101, wherein the infliximab is in a gel form.

Claim 103 (original): The method of claim 86, wherein the administration of infliximab is performed by delivering a therapeutically effective dosage of infliximab at least once prior to index conception cycle day one.

Claim 104 (original): The method of claim 86, wherein the step of the administration of infliximab is performed by delivering a therapeutically effective dosage of infliximab at least once on index conception cycle day one.

Claim 105 (original): The method of claim 86, wherein the administration of infliximab is performed by delivering a therapeutically effective dosage of infliximab at least once after index conception cycle day one.

Claim 106 (original): The method of claim 86, wherein the subject further receives lymphocyte immunization or autoimmune treatment.

Claim 107 (original): The method of claim 86, wherein the subject further receives intravenous immunoglobulin G.

Claim 108 (original): The method of claim 86, wherein the subject further receives at least one anticoagulant.

Claim 109 (original): The method of claim 108, wherein one of the anticoagulants is heparin.

Claim 110 (original): The method of claim 108, wherein one of the anticoagulants is aspirin.

Claim 111 (original): The method of claim 86, wherein the subject further receives prednisone.

Claim 112 (withdrawn)

Claim 113 (previously presented): A method for treating infertility in a subject by inhibiting spontaneous abortion or implantation failure for enhancing embryo implantation,

pregnancy, or birth rates, the method comprising administering a therapeutically effective dosage level of etanercept to the subject prior to conception by the subject.

Claim 114 (original): The method of claim 113, wherein the implantation failure occurs after ART cycles.

Claim 115 (currently amended): The method of claim 114, wherein the ART ~~is~~includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 116 (original): The method of claim 113, further enhancing the ability of the subject to carry at least one embryo to term.

Claim 117 (original): The method of claim 113, wherein the subject is a human.

Claim 118 (original): The method of claim 113, wherein the subject has had one or more previous spontaneous abortions or implantation failures.

Claim 119 (original): The method of claim 118, wherein the implantation failures occur after ART cycles.

Claim 120 (currently amended): The method of claim 119, wherein the ART ~~is~~includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 121 (original): The method of claim 113, wherein the subject undergoes natural conception.

Claim 122 (original): The method of claim 113, wherein the subject undergoes ART cycles.

Claim 123 (currently amended): The method of claim 122, wherein the ART ~~is~~includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 124 (original): The method of claim 113, wherein the subject undergoes ovulation induction cycles.

Claim 125 (original): The method of claim 113, wherein the therapeutically effective dosage level of etanercept is from about 3 mg to about 50 mg.

Claim 126 (original): The method of claim 113, where the administration of etanercept is performed by delivering a therapeutically effective dosage level of etanercept subcutaneously.

Claim 127 (original): The method of claim 113, wherein the administration of etanercept is performed by delivering a therapeutically effective dosage level of etanercept vaginally.

Claim 128 (original): The method of claim 127, wherein the etanercept is in a gel form.

Claim 129 (original): The method of claim 113, wherein the administration of etanercept is performed by delivering a therapeutically effective dosage of etanercept at least once prior to index conception cycle day one.

Claim 130 (previously presented): The method of claim 113, wherein the administration of etanercept is performed by further delivering a therapeutically effective dosage of etanercept at least once on index conception cycle day one.

Claim 131 (previously presented): The method of claim 113, wherein the administration of etanercept is performed by further delivering a therapeutically effective dosage of etanercept at least once after index conception cycle day one.

Claim 132 (original): The method of claim 113, wherein the subject further receives lymphocyte immunization or autoimmune treatment.

Claim 133 (original): The method of claim 113, wherein the subject further receives intravenous immunoglobulin G.

Claim 134 (original): The method of claim 113, wherein the subject further receives at least one anticoagulant.

Claim 135 (original): The method of claim 134, wherein one of the anticoagulants is heparin.

Claim 136 (original): The method of claim 134, wherein one of the anticoagulants is aspirin.

Claim 137 (original): The method of claim 113, wherein the subject further receives prednisone.

Claim 138 (withdrawn):

Claim 139 (previously presented): A method for treating infertility in a subject by inhibiting spontaneous abortion or implantation failure for enhancing embryo implantation, pregnancy, or birth rates, the method comprising administering a therapeutically effective dosage level of D2E7 to the subject prior to conception by the subject.

Claim 140 (original): The method of claim 139, wherein the implantation failure occurs after ART cycles.

Claim 141 (currently amended): The method of claim 140, wherein the ART ~~is~~includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 142 (original): The method of claim 139, further enhancing the ability of the subject to carry at least one embryo to term.

Claim 143 (original): The method of claim 139, wherein the subject is a human.

Claim 144 (original): The method of claim 139, wherein the subject has had one or more previous spontaneous abortions or implantation failures.

Claim 145 (original): The method of claim 144, wherein the implantation failures occur after ART cycles.

Claim 146 (currently amended): The method of claim 145, wherein the ART ~~is~~includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 147 (original): The method of claim 139, wherein the subject undergoes natural conception.

Claim 148 (original): The method of claim 139, wherein the subject undergoes ART cycles.

Claim 149 (currently amended): The method of claim 148, wherein the ART ~~is~~includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 150 (original): The method of claim 139, wherein the subject undergoes ovulation induction cycles.

Claim 151 (original): The method of claim 124, wherein the dosage level of D2E7 is from about 5 mg to about 50 mg.

Claim 152 (original): The method of claim 139, wherein the administration of D2E7 is performed by delivering a therapeutically effective dosage level of D2E7 subcutaneously.

Claim 153 (original): The method of claim 139, wherein the administration of D2E7 is performed by delivering a therapeutically effective dosage level of D2E7 intravenously.

Claim 154 (original): The method of claim 139, wherein the administration of D2E7 is performed by delivering a therapeutically effective dosage level of D2E7 vaginally.

Claim 155 (original): The method of claim 139, wherein the administration of D2E7 is performed by delivering a therapeutically effective dosage of D2E7 at least once prior to index conception cycle day one.

Claim 156 (previously presented): The method of claim 139, wherein the administration of D2E7 is performed by further delivering a therapeutically effective dosage of D2E7 at least once on index conception cycle day one.

Claim 157 (previously presented): The method of claim 139, wherein the administration of D2E7 is performed by further delivering a therapeutically effective dosage of D2E7 at least once after index conception cycle day one.

Claim 158 (original): The method of claim 139, wherein the subject further receives lymphocyte immunization or autoimmune treatment.

Claim 159 (original): The method of claim 139, wherein the subject further receives intravenous immunoglobulin G.

Claim 160 (original): The method of claim 139, wherein the subject further receives at least one anticoagulant.

Claim 161 (original): The method of claim 160, wherein one of the anticoagulants is heparin.

Claim 162 (original): The method of claim 160, wherein one of the anticoagulants is aspirin.

Claim 163 (original): The method of claim 139, wherein the subject further receives prednisone.

Claim 164 (withdrawn):

Claim 165 (previously presented): A method for treating infertility in a subject to by inhibiting spontaneous abortion or implantation failure for enhancing embryo implantation, pregnancy, or birth rates, the method comprising administering a therapeutically effective dosage level of CDP571 to the subject prior to conception by the subject.

Claim 166 (original): The method of claim 165, wherein the implantation failure occurs after ART cycles.

Claim 167 (currently amended): The method of claim 166, wherein the ART is includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 168 (original): The method of claim 165, further enhancing the ability of the subject to carry at least one embryo to term.

Claim 169 (original): The method of claim 165, wherein the subject is a human.

Claim 170 (original): The method of claim 165, wherein the subject has had one or more previous spontaneous abortions, or implantation failures.

Claim 171 (original): The method of claim 170, wherein the implantation failures occur after ART cycles.

Claim 172 (currently amended): The method of claim 171, wherein the ART ~~is~~includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 173 (original): The method of claim 170, wherein the subject undergoes natural conception.

Claim 174 (original): The method of claim 165, wherein the administration of CDP571 is performed by delivering a therapeutically effective dosage level of CDP571 subcutaneously.

Claim 175 (original): The method of claim 165, wherein the administration of CDP571 is performed by delivering a therapeutically effective dosage level of CDP571 vaginally.

Claim 176 (withdrawn):

Claim 177 (currently amended): A method for treating infertility in a subject by inhibiting spontaneous abortion or implantation failure for enhancing embryo implantation, pregnancy, or birth rates, the method comprising administering a therapeutically effective dosage level of CDP870 to the subject prior to conception by the subject.

Claim 178 (original): The method of claim 177, wherein the implantation failure occurs after ART cycles.

Claim 179 (currently amended): The method of claim 178, wherein the ART ~~is~~includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 180 (original): The method of claim 177, further enhancing the ability of the subject to carry at least one embryo to term.

Claim 181 (original): The method of claim 177, wherein the subject is a human.

Claim 182 (original): The method of claim 177, wherein the subject has had one or more previous spontaneous abortions or implantation failures.

Claim 183 (original): The method of claim 177, wherein the subject undergoes natural conception.

Claim 184 (original): The method of claim 182, wherein the implantation failures occur after ART cycles.

Claim 185 (currently amended): The method of claim 184, wherein the ART ~~is~~includes all fertility treatments in which both eggs and sperm are handled including in vitro fertilization.

Claim 186 (original): The method of claim 177, wherein the administration of CDP870 is performed by delivering a therapeutically effective dosage level of CDP870 subcutaneously.

Claim 187 (original): The method of claim 177, wherein the administration of CDP870 is performed by delivering a therapeutically effective dosage level of CDP870 vaginally.

Claims 188-276 (withdrawn):

Claim 277 (previously presented): The method of claim 1, wherein the step of reducing the ratio of the Th1 immune response to the Th2 immune response is by vaginal delivery of a TNF- α antagonist.

Claim ~~278~~ 288 (previously presented): The method of claim 53, wherein the TNF- α antagonist is delivered vaginally.

Claim ~~279~~ 289 (previously presented): The method of claim 73, wherein the TNF- α antagonist is delivered vaginally.

Claim ~~280~~ 290 (previously presented): The method of claim 86, wherein the infliximab is delivered vaginally.

Claim ~~281~~ 291 (previously presented): The method of claim 139, wherein the D2E7 is delivered vaginally.

Claim ~~282~~ 292 (previously presented): The method of claim 165, wherein the CDP 571 is delivered vaginally.

Claim 283 ~~293~~ (previously presented): The method of claim 177, wherein the CDP870 is delivered vaginally.